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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,223	09/12/2003	Stephen D. Pacetti	50623.330	9127

7590 10/05/2005

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EXAMINER	
EDWARDS, LAURA ESTELLE	
ART UNIT	**PAPER NUMBER**
1734	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,223	PACETTI ET AL.	
	Examiner	Art Unit	
	Laura Edwards	1734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7 and 25-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7 and 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Established State of the Stent Coating Art

It is well established and conventional in the medical and/or stent coating art to utilize a catheter to hold a stent while the stent is coated with a coating material. The catheter thereby serves a dual purpose of a workholder as well as a delivery device as evidenced by Rosenbluth (US 4,893,623), see col. 13, lines 34-42.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 4-7, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al (US 5,836,965) in view of Helfrich (US 5,308,338) and Scanlon et al (US 2,845,346).

Jendersee et al teach a stent delivery device (i.e.,catheter) or workholder for supporting the stent, the device comprising a tubular support member (36) for supporting the stent, a first

cuff or retaining element (54) configured to contact one end of the stent and a second cuff or retaining element (54) to make contact with another side of the stent whereby the retaining elements can be made from any implantable material from stainless steel to polymers (see col. 7, lines 34-54). Jendersee et al are silent concerning the cuffs or retaining elements having porosity even to the extent of a closed pore system. However, it was known in the medical art, at the time the invention was made, to provide a catheter with cuffs made from porous implantantable materials from polymers to sintered metal and ceramics as evidenced by Helfrich (see col. 4, lines 31-39). It was further known in the sintered metal composite art, to enable sintered metal bodies to be made of a closed pore construction as evidenced by Scanlon et al (see col. 1, lines 15-23). In light of the teachings of Jendersee et al that any implantable material can be used to make the retaining elements, the teaching of Helfrich with respect to catheters having cuffs made from porous material (i.e., sintered metal), and the teaching of Scanlon et al, that sintered metal while porous, can be made to have a closed pore system, would have found it obvious to make the retaining elements of any appropriate porous and/or non-porous implantable material so as to retain the stent on the catheter in the Jendersee et al device as well as enable the catheter with the stent thereon to be used in or out of the body. Furthermore, it would have been obvious to one of ordinary skill in the art to utilize any appropriate porous or nonporous implantable material from which to make the retaining elements, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Acknowledgement is made of Applicants' use of the claimed apparatus for coating the stent, however, the intended use of the apparatus has been given no patentable weight without

the positive recitation in the body of the claim of the structure or means for effecting coating of the stent.

With respect to the pore size, it is within the level of ordinary skill in the art to determine, via routine experimentation, the appropriate pore size including diameter of the material used to make the retaining elements.

Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al (US 5,836,965) in view of Helfrich (US 5,308,338).

Jendersee et al teach a stent delivery device (i.e., catheter) or workholder for supporting the stent, the device comprising a tubular support member (36) for supporting the stent, a first cuff or retaining element (54) configured to contact one end of the stent and a second cuff or retaining element (54) to make contact with another side of the stent whereby the retaining elements can be made from any implantable material from stainless steel to polymers (see col. 7, lines 34-54). Jendersee et al are silent concerning the cuffs or retaining elements having a porous layer thereon capable of absorbing or at least partially absorbing a fluid. However, it was known in the medical art, at the time the invention was made, to provide a catheter with cuffs made from porous implantantable materials (i.e., polymers to sintered metal and ceramics) to promote ingrowth of tissue as evidenced by Helfrich (see col. 4, lines 31-39). It would have been obvious to one of ordinary skill in the art to make the cuffs or retaining elements of a porous layer material as taught by Helfrich in the device of Jendersee et al in order to enable the absorption or retention of fluid when the stent is pretreated or enable tissue growth when device is implanted. Furthermore, it would have been obvious to one of ordinary skill in the art to utilize

any appropriate porous or nonporous implantable material from which to make the retaining elements, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Acknowledgement is made of Applicants' use of the claimed apparatus for coating the stent, however, the intended use of the apparatus has been given no patentable weight without the positive recitation in the body of the claim of the structure or means for effecting coating of the stent.

Claims 1, 2, 4-6, and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch (US 4,906,423) in view of Dustrude et al (US 5,911,752).

Frisch teaches a support mandrel for manufacturing a prosthetic device or stent comprising a shaped member configured to support a stent, the member having a plurality of pores disposed on a surface thereof wherein the pores are capable of receiving a coating substance during a coating process wherein the pores can include open to closed cells (see col. 3, lines 60- 62). Even though Frisch recognizes that at least some of the cells should be open (col. 3, lines. 60-65, Frisch remains to include in the range of cell construction, closed cells as would be determined via routine experimentation in accordance with the foam material employed. Frisch does not recognize the mandrel comprising a first element and a second element to contact both sides of the stent, however, the use of a mandrel or work support of a dumbbell shape having end elements capable of contacting opposite sides of stent is known in the medical art as evidenced by Dustrude et al (see Fig. 1f). It would have been within the purview of one skilled

in the art to shape the porous mandrel as taught by Frisch in a dumbbell form as taught by Dustrude in order to retain or secure the stent in place between the two end elements of the mandrel as the stent is processed.

Applicants' use of the term "comprising" is deemed open ended language which would not exclude the teachings of Frisch to the use of a few open cells in combination with a closed pore system.

With respect to claim 2, even though Frisch teaches that the pore size and density of the porous surface is controlled by cell size and density of foam material employed (see col. 3, lines 67+ to col. 4, lines 1-22), Frisch is silent concerning the pore diameter of .2 to 50 microns. However, one of ordinary skill in the art would determine via routine experimentation the appropriate foam material to use having a desired pore diameter in accordance with the medical device being produced and the amount of coating material sought to be absorbed on the supported mandrel.

With respect to claims 4-6, 25, and 26, see Frisch, col. 3, lines 60 to col. 4, lines 1-30.

With respect to claims 31 and 32, Applicants recitation of the absorbent material to partially absorb coating material is acknowledged, however, the device as defined by the combination above would still at least partially absorb coating material based upon the type of polymeric foam material used to make the mandrel.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patent discloses the state of the art with respect to a mandrel having

cuffs used for holding a stent during coating: Taylor et al (US 6,214,115). The following patent discloses the state of the medical art with respect to a catheter having grooved (open to closed configuration) cuff: Inoue et al (US 4,798,585).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura Edwards
Primary Examiner
Art Unit 1734

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September 30, 2005